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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,673	02/23/2004	Conceicao Minetti	13564-105004US3	3568
65989	7590	06/17/2009		
KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			06/17/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/785,673	<b>Applicant(s)</b> MINETTI ET AL.	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-21 and 27-40 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 32-40 is/are allowed.
- 6) ☒ Claim(s) 17-21 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 03/18/09 in response to the non-final Office Action mailed 10/20/08.

### **Status of Claims**

- 2) Claim 17 has been amended via the amendment filed 03/18/09.

Claims 16-21 and 27-40 are pending.

Claims 16-21 and 31-40 are under examination.

It is noted that Applicants have amended claim 17 to delete the previously presented variant species and to include additional patentably distinct species not presented previously for examination. Accordingly, the Office has moved on to the next patentably distinct species in the amended claim 17. The SEQ ID NO: 1 species has been examined.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Withdrawn**

- 5) The rejection of claim 20 made in paragraph 19(a) of the Office Action mailed 02/15/08 and maintained in paragraph 13 of the Office Action mailed 10/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 6) The rejection of claim 21 made in paragraph 19(c) of the Office Action mailed 02/15/08 and maintained in paragraph 14 of the Office Action mailed 10/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

- 7)** The rejection of claim 17 and the dependent claims 18-21 and 31 made in paragraph 16 of the Office Action mailed 10/20/08 under 35 U.S.C § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to claim 17.
- 8)** The rejection of claim 17 made in paragraph 18(a) of the Office Action mailed 10/20/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 9)** The rejection of claim 17 made in paragraph 18(b) of the Office Action mailed 10/20/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 10)** The rejection of claim 17 made in paragraph 18(c) of the Office Action mailed 10/20/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11)** The rejection of claim 17 made in paragraph 18(d) of the Office Action mailed 10/20/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 12)** The rejection of claims 18-21 and 31 made in paragraph 18(d) of the Office Action mailed 10/20/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

### **New Rejection(s) Necessitated by Applicants' Amendment**

#### **Rejection(s) under 35 U.S.C. § 103**

- 13)** The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

**14)** Claims 17-21 and 31 are rejected under 35 U.S.C § 103(a) as being unpatentable over Lock *et al.* (*Microbial Pathogenesis* 21: 71-83, 1996) in view of Paton *et al.* (*Infect. Immun.* 54: 50-55, 1986) or Walker *et al.* (*Infect. Immun.* 55: 1184-1189, 1987).

It is noted that SEQ ID NO: 1 represents the nucleic acid molecule of wild-type pneumolysin of serotype 14 *S. pneumoniae*. See Figure 1

Lock *et al.* taught a pneumolysin-producing strain of type 14 *S. pneumoniae* which comprises the nucleotide sequence of the pneumolysin. See paragraph bridging pages 78 and 79.

Lock *et al.* do not expressly teach a recombinant nucleic acid molecule comprising the pneumolysin nucleic acid sequence of wild-type serotype 14 *S. pneumoniae*, i.e., SEQ ID NO: 1.

However, Paton *et al.* taught how to routinely obtain and clone a recombinant pneumolysin DNA from a strain or serotype of *S. pneumoniae*. A recombinant *E. coli* cell comprising a plasmid vector that comprises the DNA is taught. See abstract and Materials and Methods.

Likewise, Walker *et al.* taught the routine isolation of a recombinant pneumolysin DNA from a strain or serotype of *S. pneumoniae* and cloning it. A recombinant *E. coli* cell comprising a plasmid vector that comprises the DNA is taught. See abstract; and Materials and Methods.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to obtain the recombinant pneumolysin nucleic acid molecule from Lock's pneumolysin-producing serotype 14 *S. pneumoniae* using Paton's or Walker's method of obtaining a recombinant pneumolysin nucleic acid or DNA to produce the instant invention with a reasonable expectation of success. Given the routine practice in the art of isolating and cloning pneumolysin DNA from strains of *S. pneumoniae* as demonstrated by Lock *et al.* or Paton *et al.*, one of ordinary skill in the art would have been motivated to produce the instant invention for the expected of cloning and expressing pneumolysin recombinantly from Lock's serotype 14.

Claims 17-21 and 31 are *prima facie* obvious over the prior art of record.

### Remarks

**15)** Claims 17-21 and 31 stand rejected. Claims 16 and 32-40 are allowable.

**16)** Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**17)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**18)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**19)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/  
Primary Examiner  
AU 1645

June, 2009